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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,258	09/12/2005	Alastair Dent	53037-7007	7061

66228 7590 10/22/2010

UNGARETTI & HARRIS LLP
INTELLECTUAL PROPERTY GROUP - PATENTS
70 WEST MADISON STREET
SUITE 3500
CHICAGO, IL 60602-4224

EXAMINER	
PILKINGTON, JAMES	
ART UNIT	**PAPER NUMBER**
3656	

NOTIFICATION DATE	DELIVERY MODE
10/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDOCKET@UHLAW.COM

Office Action Summary	Application No.	Applicant(s)	
	10/526,258	DENT, ALASTAIR	
	Examiner	Art Unit	
	JAMES PILKINGTON	3656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10,15-18 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10,15-18 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 13, 2010 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the surgical saw (claims 26 and 29) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 26 and 29 recite the limitation of a "surgical saw", however the disclosure as original filed did not provided support for the cutting tool to be limited to a surgical saw. Limiting of a genus to a specific species without support in the original filing is considered new matter since it could not be determined at the time of filing the type of cutting tool being used. For the purpose of examination "surgical saw" is being examined as if it is limited to any type of cutting tool as originally disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, 9, 15-17, 24, 25, 26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, WO 02/060653, in view of Akin, USP 4,565,104.

Regarding claims 1, 8, 9, 15-17, 24 and 25, Harris discloses a back-drivable surgical robot head comprising:

- a frame (6)
- an arm (12) for carrying a tool (14) the position of which is to be controlled;
- a manually-graspable driving member (16) on said arm (12);
- a first rotation control mechanism (20) for rotating the arm about a first axis (A1) with respect to said frame (6)
- the first rotation control mechanism (28) comprising a first rotational motor (30)
- in which the first motor (30) is mounted for pivotal motion with respect to a frame of the head
- said head being back-drivable wherein manual forces applied to said driving member (16) by a user grasping said driving member (16) cause said arm (12) to rotate to a desired position, said motor (30) responding to said manual forces to ensure that said arm moves smoothly to said position with constant low resistance in an unconstrained region (RI) and

with increasing resistance towards a constraint boundary (increasing resistance in RII, see the graph in figure 3 and pages 9-11 which discuses the boundary control and increasing stiffness/resistance)

- a second rotation control mechanism (20) for rotating the arm about a second axis (A1), the said mechanism comprising a second rotational motor (2)
- the first axis (A2) is perpendicular to the second axis (A1)
- the arm (12) is extendible along a third axis (A3)
- in which the first (A2), second (A1) and third axes (A3) intersect at a point
- a force sensor (18) for sensing forces applied to the driving member (16) by a user;
- wherein the first rotational control mechanism (28) is arranged to rotate the arm about the first axis in response to the sensed forces.

Harris does not disclose that the rotation control mechanisms comprising a lead screw having a rotational motor at one end and said lead screw and motor being mounted at said one end to pivot with respect to a frame and a bearing which moves longitudinally of the lead screw as it rotates, the bearing being pivotally coupled to an offset crank of or secured to the arm.

Akin teaches rotation control mechanisms comprising a motor (29), a lead screw (24) wherein the motor (29) and the lead screw (24) a mounted at said one end to pivot with respect to a frame (12 pivots about 15 which is secured to an exterior frame) and a bearing (37) which moves longitudinally of the lead screw (24) as it rotates, the bearing

being pivotally coupled to an offset crank (32) of or secured to an arm (34/35) for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load.

It would have been obvious to one having ordinary skill in the art to modify Harris and provide a first and second rotation control mechanism that comprises a lead screw and a bearing which moves longitudinally of the lead screw as it rotates, and motor being mounted at said one end to pivot with respect to a frame, the bearing being pivotally coupled to an offset crank of or secured to the arm, the lead screw has a high lead angle, resulting in the lead screw being mounted for pivotal motion with respect to a frame of the head, as taught by Akin, for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load. In additional substituting one transmission mechanism for another would have been obvious to one having ordinary skill in the art. The combination would result in a device which would operate with a lead screw which would pivot between a zero position and a maximum pivot position relative to the frame when an applied force is sensed.

Regarding claim 26, Harris discloses a back-drivable surgical robot head comprising:

- a frame (6,8) having an upper portion (6) rotatably mounted on a lower portion (8, the two parts move relative to each other)

- an arm (12) rotatable about a vertical yaw axis (A1) in communication with the lower portion of the frame and extending outwardly therefrom when the arm (12) is adapted for carrying a surgical saw (cutting tool 14/15) the position of which is to be controlled;
- a manually-graspable driving member (16) on said arm (12);
- a means for controlling a rotational movement of the arm about the vertical yaw axis (20) comprising a rotational motor (2) in operative communication with a drive transmission
- wherein the surgical robot head is back-drivable upon a manual force applied to the driving member (16) by a user grasping said driving member (16) cause said arm (12) to rotate to a desired position, said motor (30) responding to said manual forces to ensure that said arm moves smoothly to said position with constant low resistance in an unconstrained region (RI) and with increasing resistance towards a constraint boundary (increasing resistance in RII, see the graph in figure 3 and pages 9-11 which discuses the boundary control and increasing stiffness/resistance)

Harris does not disclose that the rotation control mechanisms comprising a lead screw having a rotational motor at one end and said lead screw and motor being mounted at said one end to pivot with respect to a frame and a bearing which moves longitudinally of the lead screw as it rotates, the bearing being pivotally coupled to an offset crank of or secured to the arm.

Akin teaches rotation control mechanisms comprising a motor (29), a lead screw (24) wherein the motor (29) and the lead screw (24) a mounted at said one end to pivot with respect to a frame (12 pivots about 15 which is secured to an exterior frame) and a bearing (37) which moves longitudinally of the lead screw (24) as it rotates, the bearing being pivotally coupled to an offset crank (32) of or secured to an arm (34/35) for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load.

It would have been obvious to one having ordinary skill in the art to modify Harris and provide a first and second rotation control mechanism that comprises a lead screw and a bearing which moves longitudinally of the lead screw as it rotates, and motor being mounted at said one end to pivot with respect to a frame, the bearing being pivotally coupled to an offset crank of or secured to the arm, the lead screw has a high lead angle, resulting in the lead screw being mounted for pivotal motion with respect to a frame of the head, as taught by Akin, for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load. In additional substituting one transmission mechanism for another would have been obvious to one having ordinary skill in the art. The combination would result in a device which would operate with a lead screw which would pivot between a zero position and a maximum pivot position relative to the frame when an applied force is sensed.

Regarding claim 29, Harris discloses a method of using a surgical saw comprising the steps of: providing a surgical robot head having a frame (6,8) with an

upper portion (6) rotatably mounted on a lower portion (8, the two parts move relative to each other), an arm (12) rotatable about a vertical yaw axis (A1) in communication with the lower portion of the frame and extending outwardly therefrom when the arm (12) is adapted for carrying a surgical saw (cutting tool 14/15) the position of which is to be controlled, a manually-graspable driving member (16) on said arm (12), a means for controlling a rotational movement of the arm about the vertical yaw axis (20) comprising a rotational motor (2) in operative communication with a drive transmission and back driving the surgical robot head by applying manual forces to the driving member (16) by a user grasping said driving member (16) cause said arm (12) to rotate to a desired position wherein the motor (30) responds to said manual forces to ensure that said arm moves smoothly to said position with constant low resistance in an unconstrained region (RI) and with increasing resistance towards a constraint boundary (increasing resistance in RII, see the graph in figure 3 and pages 9-11 which discusses the boundary control and increasing stiffness/resistance, and page 12 lines 15-25 which discusses the communication between the handle and the motor which moves/back drives the device)

Harris does not disclose that the rotation control mechanisms is provided with a lead screw having a rotational motor at one end and said lead screw and motor being mounted at said one end to pivot with respect to a frame and a bearing which moves longitudinally of the lead screw as it rotates, the bearing being pivotally coupled to an offset crank of or secured to the arm.

Akin teaches rotation control mechanisms comprising a motor (29), a lead screw (24) wherein the motor (29) and the lead screw (24) a mounted at said one end to pivot with respect to a frame (12 pivots about 15 which is secured to an exterior frame) and a bearing (37) which moves longitudinally of the lead screw (24) as it rotates, the bearing being pivotally coupled to an offset crank (32) of or secured to an arm (34/35) for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load.

It would have been obvious to one having ordinary skill in the art to modify Harris and provide a first and second rotation control mechanism that comprises a lead screw and a bearing which moves longitudinally of the lead screw as it rotates, and motor being mounted at said one end to pivot with respect to a frame, the bearing being pivotally coupled to an offset crank of or secured to the arm, the lead screw has a high lead angle, resulting in the lead screw being mounted for pivotal motion with respect to a frame of the head, as taught by Akin, for the purpose of providing a linear actuator to rotate a load that minimizes loss of moment arm at the extremes of rotational travel of the load. In additional substituting one transmission mechanism for another would have been obvious to one having ordinary skill in the art. The combination would result in a device which would operate with a lead screw which would pivot between a zero position and a maximum pivot position relative to the frame when an applied force is sensed and meets the limitation of the method since all the structural elements of the device have been provided for in the combination.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, WO 02/060653, in view of Akin, USP 4,565,104 and further in view of Yamanaka, USP 4,825,714.

Harris in view of Akin discloses all of the claimed subject matter discussed above.

Akin does not disclose that the motor is directly secured to the lead screw, without any intervening gears.

Yamanaka teaches a lead screw drive arrangement wherein the motor (11) is directly secured to the lead screw (15), without any intervening gears.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the motor spindle arrangement of Akin with the direct drive system of Yamanaka, for the predictable result of removing play/backlash that is found between intervening gears.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, WO 02/060653, in view of Akin, USP 4,565,104 and further in view of Zufle, US PGPub 2003/0109953.

Harris in view of Akin discloses all of the subject mater as discussed above.

Harris does not disclose a first sensor for measuring the position of the arm and a second sensor for measuring the rotation of the motor and sounding an alarm if there is an inconsistency.

Zufle teaches a detection system which uses a first sensor for measuring the position of an arm/movement member (detector 5) and a second sensor for measuring the rotation of the motor (paragraph 0025) and sounding an alarm if there is an inconsistency (sets down drive 3 or paragraph 0017) for the purpose of providing a direct and indirect detection method to ensure movement of the arm is correct (paragraph 0015 and 0025).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Harris and provide a first sensor for measuring the position of the arm and a second sensor for measuring the rotation of the motor and sounding an alarm if there is an inconsistency, as taught by Zufle, for the purpose of providing a direct and indirect detection method to ensure movement of the arm is correct.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, WO 02/060653, in view of Akin, USP 4,565,104 and further in view of Zimmerman, USP 6,494,005.

Harris in view of Akin discloses all of the subject matter as discussed above.

Harris does not disclose that the arm is extendible on a third lead screw which is rotated by a third rotational motor.

Zimmerman teaches an arm (12) extendable on a lead screw (50) which is rotated by a motor (30) for the purpose of concealing the motor within an arm segment (C1/L45-52) which in turn reduces the size of the device.

It would have been obvious to one having ordinary skill in the art to replace the rack and pinion drive system of Harris with a third lead screw which is rotated by a third rotational motor, as taught by Zimmerman, for the purpose of concealing the motor within an arm segment which in turn reduces the size of the device.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris, WO 02/060653, in view of Akin, USP 4,565,104 and further in view of Ghodoussi, US PGPub 2003/0144649.

Harris discloses all of the claimed subject matter as applied to claim 26 above. Harris also discloses a guide track (11/13) supporting a portion of the arm (12, supports the outer shell of the arm) [Claim 28].

Harris does not disclose that the device also a locking handle attached to the arm.

Ghodoussi teaches that a surgical robot can be provided a locking handle (118) attached to the arm (handle 118 is attached the graspable knob 102 which is connected to an arm 56/66) for the purpose of locking the end effector (tool) in place (see paragraph 0044).

It would have been obvious to one having ordinary skill in the art to modify Harris and add a locking handle attached to the arm, as taught by Ghodoussi, for the purpose of locking the end effector in place when movement is not desired.

Response to Arguments

Applicant's arguments filed March 15, 2010 and October 12, 2010 have been fully considered but they are not persuasive.

The Applicant argues that the linear actuator of Akin is not back drivable and thus the combination not proper.

Any linear screw and nut system, as in the Akin reference and the instant application, is back drivable regardless of the thread pitch. The claim does not recite any specific back drivable structure and a screw and nut system can be driven in reverse, either by hand or a motor. In the case of Akin the device is attached to a motor which can be run in forwards and reverse thus making the system back drivable. The Applicant, in the Remarks dated October 12, 2010 and March 15, 2010 goes into detail about the "back-drivablility" being the ability of a user to apply an external force to the manually graspable driving member and for that force to be transmitted back along the gear chain to the input motor but the claim does not recite any type of "gear chain." The primary reference to Harris discusses the drive units and the back drivablitiy of the system by detecting the force at the handle and moving the motors according to that force which is the same type of communication between the motor and handle as discussed Applicant's specification on page 4 line 25 - page 5 line 3. Using the "back-drivable" system of Harris with the sensors, handle and motors with a different mechanical force transmitting system, replacing a gear transmission with a lead screw transmission, would indeed result in a back drivable system that uses a lead screw as the motion transmitting mechanism.

On March 13, 2010, the Applicant also provided supporting evidence for a meaning of “back-drivability.” However, as stated above, the combination of Harris and Akin results in a device which meets this definition; this “back-drivability" feature is found in the primary reference to Harris and is the same as that of the instant application. The replacement of the drive system of Harris with that of Akin does not alter the operation of the device of Harris and results in a back drivable device. In addition, the specification as originally filed did not limit "back-drivable" to mean that the device has the ability to switch the input with the output. The specification, in paragraph 0039, defined back drivable as a response to a pull from the surgeon and does not limit the arrangement to one where the force of the user rotates the shaft directly or moves a “gear chain”. The arrangement of Akin responses to a pull from the surgeon, through a system of sensors and motors, and therefore meets the constraints of the term "back-drivable" as originally set forth by the Applicant. Also, the supporting documentation provided by the Applicant relates to Anthropomorphic Robot Hands, not a surgical robot arm operated by a user. The backdrivability discussed in this document is concerned with providing flexibility to the system not a backwards driving force. Outside the section underlined by the Applicant the introduction of the document states that “backdrivability plays a large role in actuator flexibility and force controllability” and “without backdrivability, actuators had to realize flexibility by either adding elastic components in series to the actuator output, or by control.” The document later goes on to state that the backdrivability/flexibility “of the actuation is especially effective in grasping and manipulating of the objects. Since grasping involves multiple point

contacts with uncertainty, robot hands need to deal with uncertain complicated force interaction", in other words backdrivability, in the case of this document, is the ability of an actuator to adjust to the object being worked upon (i.e. the robotic hand won't crush the object it is handling). Since this document is clearly relating to the movement of robot hands and not the movement of an arm in response to a user it appears that this definition is not analogous to the instant application.

With regards to the Applicant's comments about in the Mechanical Arrangement of Akin section of the remarks: the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). That fact that Akin deals with a large angle of rotation and is not a surgical robotic device does not mean that one of ordinary skill in the art would not look to the disclosure of Akin and appreciate that the same motion transmitting arrangement (linear to rotary) can be used in other environments and within limited operation ranges. Modifications to fit a particular operation range for a particular environment are within the level of ordinary skill in the art. Also, it is noted that the features upon which applicant relies (i.e., small pivot angle and maximal pivot position, and a case) are not recited in the rejected claim(s). Although the claims are interpreted

in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES PILKINGTON whose telephone number is (571)272-5052. The examiner can normally be reached on Monday - Friday 7-3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Ridley can be reached on (571)272-6917. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES PILKINGTON/
Examiner, Art Unit 3656
10/18/10